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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,555	09/22/2000	Ypke Vincentius Johannes Maria van Oosterhout	4541US	2631

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/668,555	VAN OOSTERHOUT ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claim 1 is under consideration.

2. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claim.

3. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Scannon (WO 89/06967) for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claim.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scannon (WO 89/06967) in view of Thorpe et al.

Scannon teaches use of a pharmaceutical composition containing the immunotoxins antiCD3 antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon teaches that the immunotoxin can be prepared by chemical linkage using art known

methods such as use of heterobifunctional crosslinkers (see page 5). Scannon discloses that the antibody can be of the IgG isotype (see page 6, second paragraph) wherein IgG2B is one of the four art known types of IgG. Thus the routineer would at once envisaged IgG2B, because IgG2B is one of the four art known types of IgG. See *In re Schauman,* 572 F.2d 312, 197 USPQ 5 (CCPA 1978) and *In re Peterinq*, 301 F.2d 676, 681, 133 USPQ 275,280 (CCPA 1962). Furthermore, Scannon also discloses use of antibodies of the IgG2B isotype in Table 1 (such as OKT4, etc).

In the decision of the BPAI 4/28/06, the Board stated:

"Upon consideration of the reference, we find that while Scannon teach (e.g. page 9), alternative immunotoxin compositions, Scannon specifically teach "in one embodiment of the present invention, an immunosuppressive immunotoxin composition will comprise at least one pan T-cell immunoglobulin reactive agent, e.g., reactive with the CD3, CD5 or CD7 antigen clusters." ***In our opinion, one of skill in the art reading this teaching in Scannon would immediately envisage a small class of seven compositions with common properties. In re Peterinq, 301 F.2d 676, 681, 133 USPQ 275,280 (CCPA 1962). Specifically, compositions that will comprise a molecule reactive with: (1)CD3; (2) CD5; (3) CD7; (4) CD3 and CD5; (5) CD3 and CD7; (6) CD5 and CD7;or (7) CD3, CD5 and CD7. Stated differently, we understand Scannon's use of the phrase "at least one pan T-cell immunoglobulin reactive agent, e.g reactive with the CD3, CD5 or CD7 antigen clusters," to represent a short-hand way of expressing the seven compositions set forth above.*** *In addition, we note that while the title of the Scannon reference is "immunosuppression with anti-pan T cell immunotoxin compositions," the only anti-pan T cell immunoglobulin reactive agents taught by Scannon, are CD3, CD5 and CD7. See e.g, Scannon, page 9. Further, as set forth on page 4 of Scannon, "[t]he cytotoxic agent component of the immunotoxin is preferably a ribosomal inhibiting protein, such as ricin or ricin A-chain." Accordingly, we agree with the examiner's finding that Scannon teach a*

pharmaceutical composition containing the immunotoxins anti-CD3-ricin A and anti-CD7-ricin A.".

Applicants comments regarding this analysis were further addressed in the BPAI decision of 7/31/06 denying a request for rehearing.
Scannon does not teach the linker used is SMPT. Thorpe et al. teach use of the heterobifunctional crosslinker SMPT in an immunotoxin containing ricin and an antibody (see abstract). Thorpe et al. disclose that use of SMPT strongly improves the antitumor effect of the immunotoxin (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Scannon et al. teaches the claimed invention except for use of the heterobifunctional crosslinker SMPT, Scannon teaches that the immunotoxin can be prepared by chemical linkage using art known methods such as use of heterobifunctional crosslinkers whilst Thorpe et al. teach use of the heterobifunctional crosslinker SMPT in an immunotoxin containing ricin and an antibody and that use of SMPT strongly improves the antitumor effect of the immunotoxin. One of ordinary skill in the art would have been motivated to do the aforementioned because Scannon teaches that the immunotoxin can be prepared by chemical linkage using art known methods such as use of heterobifunctional crosslinkers and Thorpe et al. teach use of the heterobifunctional crosslinker SMPT in an immunotoxin containing ricin and an antibody and that use of SMPT strongly improves the antitumor effect of the immunotoxin.

6. No claims are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until

after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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